## DETAILED ACTION

### *Final Rejection*

1. The text of those sections of title 35 U.S.C. not included in this action can be found in a prior Office action.

2. The Objection to claim 26 is hereby withdrawn in light of Applicant's amendments.

3. The Objection to the specification for lack of an abstract is withdrawn. Applicant's abstract was indeed present in the application prior to the Examiner's first action. The Examiner regrets the error.

4. Applicants' response filed 10/11/07 is acknowledged.

5. Claims 1, 7, 10, 13-22, 25-47 and 49-61 are examined.

### *Claim Objections*

6. Claim 7 is objected to because Claim 7 contains two periods. MPEP 608.01(m).

7. Claim 10 is objected to because Claim 10 contains a superfluous comma: ". . . comprising, the nucleic acid of claim 1. . ."

8. Claim 1 and its dependents are objected to because of the following informalities: Claim 1(b) contains a typographical error. Claim 1(b) recites "a nucleic acid molecule less than 486 amino acids." It is believed Applicant intended to recite "a nucleic acid molecule encoding an amino acid molecule less than 486 amino acids . . .." Appropriate correction is required.

### *Claim Rejections - 35 U.S.C. §103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. §103(a).

The *Graham* court set forth the factual inquiries that are applied for determining obviousness under 35 U.S.C. 103(a):

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

*Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 7, 10, 13-22, 25-47 and 49-61 are rejected under 35 U.S.C. 103(a) as obvious over et al (Harper 1, WO 2002/16655, published 28 February 2002, filed) in light of Harper et al (Harper 2, Genbank Database. Accession No. AX510060, WO 2002/16655, SEQ ID NO: 2071, 28 February 2002) and Harper et al (Harper 3, Genbank Database. Accession No.

AX507376, WO 2002/16655: SEQ ID NO: 4755, 28 February 2002). The claims are broadly drawn to a hydroxypyruvate promoter, compositions therewith, and methods of using same. The amended rejection as applied under 35 USC 103 is maintained for reasons of record set forth in the Official action mailed 7/11/07. Applicants arguments filed 10/11/07 have been fully considered but are deemed not persuasive.

***Response to Arguments***

Applicant traverses primarily that with respect to SEQ ID NO:4755, there is nothing in Harper 1 et al. that discloses anything less than the 487 base pair sequence of SEQ ID NO:4755 in its entirety as having promoter activity. (Response dated 10/11/07, page 7-8). This is not persuasive because making truncations of promoters is obvious and routine. Skilled artisans routinely make truncations to obtain the smallest possible promoter retaining function. Smaller promoters are preferable because they conserve space in cloning vectors. Moreover, Harper 1 discloses "functional portion[s]" of SEQ ID NO: 4755. (*Id.* @ 3:20-21).

Applicant traverses primarily that Harper 1 et al. does not anticipate the claimed invention because SEQ ID NO: 4755 will function as an inducible promoter while Applicants' amended claims are to a constitutive promoter. (Response, page 7-8). This is not persuasive. As stated above, skilled artisans routinely make promoter truncations. The truncated promoter would inherently have the same functional characteristics because it would have the same structure.

It is well known that making truncations frequently results in the creation of a constitutive core promoter sequence. The process of truncating a promoter frequently removes promoter elements responsible for promoter activity. For example removal of promoter

sequences involved in repression/derepression could convert a normally repressed promoter with regulated expression into a constitutive promoter. Sing teaches that loss of proper Id-1 repression site (-1200 to -932) of the Id-1 promoter converts the promoter into a constitutive promoter leading to aggressive metastatic breast cancer. (Singh, et al. Constitutive expression of the Id-1 promoter in human metastatic breast cancer cells is linked with the loss of NF-1/Rb/HDAC-1 transcription repressor complex 14 2002, Volume 21, Number 12, Pages 1812-1822). That Applicant's truncated promoter operates differently than allegedly Harper1's promoter is merely an inherent feature of a composition arrived at by routine experimentation.

The Examiner has fully considered the note by Applicants that the 3' terminal sequence of SEQ ID NO: 5 (CCATGGCG) represents a restriction site for the NcoI (CCATGG) enzyme and that this finds convenient use in operably linking the promoter sequence to a sequence of interest to be expressed. (Response, page 8). Adding a cloning site to a promoter during vector construction prior to making transgenic plants is obvious. Applicant's particular choice of restriction site is design/expression vector choice and is not critical. The addition of the six nucleotides to the end of the promoter for the purpose convenience of vector construction causes the downstream end of Harper 1's SEQ ID NO: 4755 to be 100% identical to Applicant's SEQ ID NO: 5. This causes Harper 1's SEQ ID NO: 4755 to be identical to Applicant's SEQ ID NO: 5 save for an additional 206 nucleotides upstream of Harper 1's SEQ ID NO: 4755. Because making truncations of promoters is routine, only routine experimentation is needed to arrive at the sequence of Applicant.

Harper 1's first two codons of the coding regions of the structural gene – atg-gcg – for HPR are the same as the last six nucleotides – atg-gcg – of Applicant's "promoter."

According to Applicants themselves, Applicant has added an NcoI restriction site onto the end of the promoter, and this restriction site is not part of the promoter. (Response, page 7-8). Applicant's admission that they added an NcoI restriction site onto the end of the promoter shows that the sequence was arrived at by routine methods and not undue experimentation. (Response, page 7-8). Adding restriction sites for cloning is obvious. Making truncations of a promoter is also an obvious design step. It is well known that promoter truncations are routinely made. Thus using only two obvious methods, truncating and then adding a restriction site, the promoter of Harper 1 is converted into the promoter of Applicant: "consisting of SEQ ID NO:5."

Harper 1 teaches SEQ ID NO: 4755 which is 97.9% identical to Applicant's SEQ ID NO: 5. and SEQ ID NO: 2071, the hydroxypyruvate reductase (HPR) enzyme coding sequence beginning with an atg-gcg for methionine and alanine which are the first two codons of said enzyme. Harper 1 teaches an isolated nucleic acid molecule comprising SEQ ID NO: 5. (See sequence listing for SEQ ID NO: 2071 and 4755, page 5, lines 10-11; sequence listing; Table 1 on page 111; Table 2 on page 139).

Adding restriction sites for cloning is obvious. Making truncations of a promoter is also an obvious design step. It is well known that promoter truncations are routinely made. Thus using only two obvious methods, truncating and then adding a restriction site, the promoter of Harper 1 is converted into the promoter of Applicant: "consisting of SEQ ID NO:5."

Promoter choice is non-critical routine design choice. Regarding whether the promoter was known in the art, Harper 1 describes the promoter, teaches the boundaries of the full length, and teaches that it is a regulatory element.

Harper 1 teaches an isolated nucleic acid construct (page 15, line 14; page 5, line 27) consisting of Applicant's SEQ ID NO: 5 operably linked to a nucleotide sequence encoding a heterologous gene (page 5, line 19), wherein said construct further comprises a selectable marker or reporter gene, wherein said heterologous gene encodes a farnesyl transferase alpha protein of interest (SEQ ID NO: 701), wherein said heterologous gene is capable of altering an agronomic trait, wherein said agronomic trait is herbicide resistance or increased yield (p. 58, Ln. 19-22), wherein said heterologous gene is a plant or structural gene (p. 1, Ln. 5, p. 3, Ln. 23; p. 35, col. 7), wherein said structural gene is an enzyme (Table 1, SEQ ID NO: 2071, SEQ ID NO: 337, SEQ ID NO: 872), a transcriptional regulator, a chaperonin protein (page 85, Table 1, SEQ ID NO: 102) or a scaffolding protein, wherein said isolated nucleic acid construct comprises a promoter comprising SEQ ID NO: 5 operably linked to a non-translatable mRNA molecule of a gene encoding a protein of interest, wherein said non-translated mRNA molecule is an antisense nucleic acid, a hairpin RNA or a micro RNA (p. 11, Ln. 26, p. 12, Ln. 25, p. 40, Ln. 21-32, p. 49, Ln 15-30).

Harper 1 teaches a monocotyledonous or dicotyledonous plant cell comprising a vector comprising a construct comprising Applicant's SEQ ID NO: 5. (page 5, lines 9-25, p. 20, Ln. 28; p. 45, Ln. 23-30, p. 64, Ln. 20-21)

Harper 1 teaches a method of producing a transgenic plant (page 5, lines 3-25) and transgenic plants and seeds therefrom, including wherein said seed produces a plant that expresses said protein of interest (page 9, lines 15-30; claim 120), said method comprising introducing into a plant cell (page 5, line 17) said vector comprising Applicant's SEQ ID NO: 5, to generate a transgenic cell and regenerating a transgenic plant from said transgenic cell,

wherein said transgenic plant expresses said protein of interest, wherein said expression is constitutive, wherein said expression is inducible 49, wherein said plant cell is monocotyledonous or dicotyledonous. (p. 64, Ln. 20-21).

Harper 1 teaches a method (page 9, lines 15-30; claim 120) of expressing a heterologous protein at a decrease level comprising introducing into a cell said construct and expressing said heterologous protein in said cell, wherein said cell is a plant cell, wherein said plant cell is monocotyledonous or dicotyledonous. (p. 40, Ln. 18-25). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add restriction sites to the promoter of Harper 1 or truncation thereof because doing so "finds convenient use in operably linking the promoter sequences to a sequence of interest to be expressed." (Response, page 8). Making truncations of a promoter is an obvious design step. It is well known that promoter truncations are routinely made and tested using, *inter alia,* transient assays. Adding an NcoI restriction-site to the promoter of Harper 1 results in the production of SEQ ID NO: 5. One of skill in the art routinely adds restriction sites such as the atg-gcg found in Applicant's SEQ ID NO: 5 to genetic elements to facilitate cloning. One of skill in the art would know to append a methionine codon, if need be, onto the downstream end of a promoter to facilitate initiation of translation. One skilled in the art would have been motivated to generate the claimed invention because blunt-end ligation without a restriction-site is not as efficient as sticky-end ligation. Further motivation comes from the knowledge of one of ordinary skill in the art that translation initiation is inefficient without an atg start codon. One skilled in the art would have done so with a reasonable expectation of success because promoter truncation and restriction-site addition are

routine in the art. The particular restriction site added is experimental design choice. Accordingly, one of ordinary skill in the art would have generated the claimed invention.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. All Claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Anne Marie Grunberg/
Supervisory Patent Examiner, Art Unit 1638